



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-2032]

Limited Population Pathway for Antibacterial and Antifungal Drugs; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled "Limited Population Pathway for Antibacterial and Antifungal Drugs." The purpose of the meeting is to provide a public forum for FDA to listen to comments on the draft guidance for industry, "Limited Population Pathway for Antibacterial and Antifungal Drugs," that was published in the *Federal Register* on June 13, 2018. FDA is also reopening the comment period on this draft guidance for comments to be submitted for consideration before we finish work on the final version of the guidance.

DATES: The public meeting will be held on July 12, 2019, from 9 a.m. to 3 p.m. Eastern Time. Submit either electronic or written comments by August 12, 2019, to ensure that the Agency considers your comments on the draft guidance before it finishes work on the final version of the guidance. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public meeting will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503A (the Great Room), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine

security check procedures will be performed. For parking and security information, please refer to

<https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-D-2032 for "Limited Population Pathway for Antibacterial and Antifungal Drugs." Received comments, will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential."

Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

FOR FURTHER INFORMATION CONTACT: Sarah Walinsky, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6242, Silver Spring, MD 20993-0002, sarah.walinsky@fda.hhs.gov, 240-402-4075; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* for June 13, 2018 (83 FR 27616), FDA announced the availability of a draft guidance for industry entitled "Limited Population Pathway for Antibacterial and Antifungal Drugs."¹ This draft guidance provides information on the implementation of section 506(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 356(h), added by

¹ <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm610498.pdf>.

section 3042 of the 21st Century Cures Act, which established the limited population pathway for antibacterial and antifungal drugs (LPAD pathway). This draft guidance is intended to assist sponsors in the development of certain new antibacterial and antifungal drugs for approval under the LPAD pathway. This draft guidance also is intended to assist sponsors in developing labeling, including prescribing information, patient labeling, and carton/container labeling, that incorporates certain statements required by section 506(h) of the FD&C Act. The LPAD pathway is intended to encourage the development of certain antibacterial and antifungal drugs for limited and specific populations of patients to help address the critical public health and patient care concern that has resulted from the current decline in antibacterial and antifungal drug research and development as serious antibacterial and antifungal drug-resistant infections increase.

FDA received numerous comments on the draft guidance from a diverse group of stakeholders. FDA also received requests for listening meetings with FDA to provide feedback concerning the draft guidance on the LPAD pathway. In view of these requests and to promote transparency, FDA will hold a public meeting at which stakeholders may present or comment on the draft guidance.

The format of the meeting involves presentations from the public. The Agency will not be inviting specific presenters; rather, with this document, FDA is soliciting presentations from interested stakeholders. FDA also invites interested persons to submit written comments to the docket established with the publication of the draft guidance on the LPAD pathway. FDA is also reopening the comment period on this draft guidance for comments to be submitted for consideration before it finishes work on the final version of the guidance. Submit either

electronic or written comments by August 12, 2019, to ensure that the Agency considers your comments on this draft before it finishes work on the final version of the guidance.

II. Topics for Discussion at the Public Meeting

FDA is holding a public meeting to receive information and comments concerning the draft guidance on the LPAD pathway from a broad group of stakeholders, including patients, researchers, healthcare providers, manufacturers, interested industry, professional organizations, and the public. The Agency has determined that a public meeting is the most appropriate way to ensure public engagement on the draft guidance. FDA welcomes any relevant information that stakeholders wish to share.

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: https://fdalimitedpopppathwayantibacterial_antifungal.eventbrite.com by July 1, 2019, at 11:59 p.m. Eastern Time. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability. Persons interested in attending this public meeting must register by July 1, 2019, at 11:59 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public meeting/public workshop will be provided beginning at 8:15 a.m. We will let registrants know if registration closes before the day of the public meeting/public workshop.

If you need special accommodations due to a disability, please contact Sarah Walinsky (see FOR FURTHER INFORMATION CONTACT) no later than July 1, 2019, at 11:59 p.m. Eastern Time.

Requests for Oral Presentations: During online registration you may indicate which topic(s) you wish to address, and an approximate desired length of your presentation, so that FDA can consider this information in organizing the presentations. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to present. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and we will select and notify participants. All requests to make oral presentations must be received by the close of registration on July 1, 2019, at 11:59 p.m. Eastern Time. If selected for presentation, any presentation materials must be emailed to the Sarah Walinsky (see FOR FURTHER INFORMATION CONTACT) no later than 12 p.m. Eastern Time July 8, 2019. No commercial or promotional material will be permitted to be presented or distributed at the public meeting. Presenters are encouraged to submit a copy of their presentation and related written material to the docket (see "ADDRESSES") in advance of the public meeting

Streaming Webcast of the public meeting: This public meeting will also be webcast via <https://collaboration.fda.gov/lppaadpm0719>

If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit https://www.adobe.com/go/connectpro_overview.

FDA has verified the website addresses in this document, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see ADDRESSES). A link to the transcript will also be available on the internet at

[https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm631810.h](https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm631810.htm)
tm.

Dated: March 28, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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